# In the United States Court of Federal Claims

**OFFICE OF SPECIAL MASTERS**
**No. 23-0496V**

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| YVONNE MCCLAY,<br><br>Petitioner,<br>v.<br><br>SECRETARY OF HEALTH AND HUMAN SERVICES,<br><br>Respondent. | Chief Special Master Corcoran<br><br>Filed: March 5, 2024 |

*Jeffrey S. Pop, Jeffrey S. Pop & Associates, Beverly Hills, CA, for Petitioner.*

*Camille Webster, U.S. Department of Justice, Washington, DC, for Respondent.*

## FINDINGS OF FACT AND CONCLUSIONS OF LAW[1]

On April 11, 2023, Yvonne McClay filed a petition for compensation under the National Vaccine Injury Compensation Program, 42 U.S.C. §300aa-10, *et seq.*[2] (the "Vaccine Act"). Petitioner alleges that she suffered a left-sided shoulder injury related to vaccine administration ("SIRVA"), a defined Table injury, after receiving an influenza ("flu") vaccine on December 2, 2020. The case was assigned to the Special Processing Unit ("SPU") of the Office of Special Masters.

For the reasons discussed below, I find that the flu vaccine was most likely administered in Petitioner's left arm, as alleged.

[1] Because this ruling contains a reasoned explanation for the action taken in this case, it must be made publicly accessible and will be posted on the United States Court of Federal Claims' website, and/or at https://www.govinfo.gov/app/collection/uscourts/national/cofc, in accordance with the E-Government Act of 2002. 44 U.S.C. § 3501 note (2018) (Federal Management and Promotion of Electronic Government Services). **This means the ruling will be available to anyone with access to the internet.** In accordance with Vaccine Rule 18(b), Petitioner has 14 days to identify and move to redact medical or other information, the disclosure of which would constitute an unwarranted invasion of privacy. If, upon review, I agree that the identified material fits within this definition, I will redact such material from public access.

[2] National Childhood Vaccine Injury Act of 1986, Pub. L. No. 99-660, 100 Stat. 3755. Hereinafter, for ease of citation, all section references to the Vaccine Act will be to the pertinent subparagraph of 42 U.S.C. § 300aa (2012).

## I. Relevant Procedural History

The Petition was accompanied by the statutorily-required supporting medical documentation and Petitioner's own declaration. Exhibits ("Exs.") 1 – 11. In July 2023, the case was assigned to the SPU. ECF No. 9. In November 2023, I adopted the parties' proposed schedule for further proceedings. ECF No. 12. Petitioner subsequently filed Exs. 12 – 16, ECF No. 14, followed by a Brief setting forth her position regarding the factual issue of the implicated flu vaccine's administration site on January 16, 2024. ECF No. 16.[3] Respondent filed a Response on February 26, 2024. ECF No. 17. I have determined that a factual finding on this issue is required and will assist in the case's ultimate disposition.

## II. Applicable Legal Standards

Pursuant to Vaccine Act Section 13(a)(1)(A), a petitioner must prove, by a preponderance of the evidence, the matters required in the petition by Vaccine Act Section 11(c)(1). A special master must consider, but is not bound by, any diagnosis, conclusion, judgment, test result, report, or summary concerning the nature, causation, and aggravation of petitioner's injury or illness that is contained in a medical record. Section 13(b)(1). "Medical records, in general, warrant consideration as trustworthy evidence. The records contain information supplied to or by health professionals to facilitate diagnosis and treatment of medical conditions. With proper treatment hanging in the balance, accuracy has an extra premium. These records are also generally contemporaneous to the medical events." *Cucuras v. Sec'y of Health & Hum. Servs*., 993 F.2d 1525, 1528 (Fed. Cir. 1993).

Accordingly, where medical records are clear, consistent, and complete, they should be afforded substantial weight. *Lowrie v. Sec'y of Health & Hum. Servs*., No. 03-1585V, 2005 WL 6117475, at *20 (Fed. Cl. Spec. Mstr. Dec. 12, 2005). However, this rule does not always apply. "Written records which are, themselves, inconsistent, should be accorded less deference than those which are internally consistent." *Murphy v. Sec'y of Health & Hum. Servs.*, No. 90-882V, 1991 WL 74931, *4 (Fed. Cl. Spec. Mstr. April 25, 1991), quoted with approval in decision denying review, 23 Cl. Ct. 726, 733 (1991), *aff'd per curiam*, 968 F.2d 1226 (Fed.Cir.1992)). And the Federal Circuit recently "reject[ed] as incorrect the presumption that medical records are accurate and complete as to all the patient's physical conditions." *Kirby v. Sec'y of Health & Hum. Servs.*, 997 F.3d 1378, 1383 (Fed. Cir. 2021).

[3] Petitioner and the additional witnesses' statements, *see* Exs. 1, 12, 14 – 16, are sworn under penalty of perjury. *See* 28 U.S.C.A. § 1746 (providing that such a declaration may be afforded "like force and effect" as an affidavit).

The United States Court of Federal Claims has outlined four possible explanations for inconsistencies between contemporaneously created medical records and later testimony: (1) a person's failure to recount to the medical professional everything that happened during the relevant time period; (2) the medical professional's failure to document everything reported to her or him; (3) a person's faulty recollection of the events when presenting testimony; or (4) a person's purposeful recounting of symptoms that did not exist. *La Londe v. Sec'y of Health & Hum. Servs*., 110 Fed. Cl. 184, 203-04 (2013), *aff'd*, 746 F.3d 1335 (Fed. Cir. 2014).

The Court has also said that medical records may be outweighed by testimony that is given later in time that is "consistent, clear, cogent, and compelling." *Camery v. Sec'y of Health & Hum. Servs*., 42 Fed. Cl. 381, 391 (1998) (citing *Blutstein v. Sec'y of Health & Hum. Servs*., No. 90-2808, 1998 WL 408611, at *5 (Fed. Cl. Spec. Mstr. June 30, 1998). The credibility of the individual offering such fact testimony must also be determined. *Andreu v. Sec'y of Health & Hum. Servs.*, 569 F.3d 1367, 1379 (Fed. Cir. 2009); *Bradley v. Sec'y of Health & Hum. Servs*., 991 F.2d 1570, 1575 (Fed. Cir. 1993).

A special master may find that the first symptom or manifestation of onset of an injury occurred "within the time period described in the Vaccine Injury Table even though the occurrence of such symptom or manifestation was not recorded or was incorrectly recorded as having occurred outside such period." Section 13(b)(2). "Such a finding may be made only upon demonstration by a preponderance of the evidence that the onset [of the injury] . . . did in fact occur within the time period described in the Vaccine Injury Table." *Id*.

The special master is obligated to fully consider and compare the medical records, testimony, and all other "relevant and reliable evidence contained in the record." *La Londe*, 110 Fed. Cl. at 204 (citing Section 12(d)(3); Vaccine Rule 8); *see also Burns v. Sec'y of Health & Hum. Servs*., 3 F.3d 415, 417 (Fed. Cir. 1993) (holding that it is within the special master's discretion to determine whether to afford greater weight to medical records or to other evidence, such as oral testimony surrounding the events in question that was given at a later date, provided that such determination is rational).

## III. Finding of Fact

I have reviewed the record to include all medical records, affidavits, documentation, briefing, and additional evidence filed. Summarized below is the evidence most pertinent to my factual finding regarding the site of vaccination.

- Petitioner received a seasonal flu vaccine nearly every year from 2013-20, with the site typically recorded as her left deltoid. *See generally* Ex. 3 at 2 – 6. In 2013 and again in 2016, she is recorded as having received a flu vaccine in her left deltoid, plus an additional vaccine in her right deltoid. *Id.* at 3 – 4, 6.

- On December 2, 2020, a registered nurse at the same primary care practice administered a flu vaccine and a recombinant zoster vaccine ("RZV," colloquially referred to as shingles)[4] to Petitioner.[5] Ex. 4 at 2. While the nursing note does not address situs, a computerized immunization history provides that *both* vaccines were administered in Petitioner's right deltoid. Ex. 3 at 3.

- Thirteen (13) days later, on December 15, 2020, Petitioner and her established primary care physician had a telehealth[6] encounter regarding various chronic conditions. The encounter does not address her recent vaccinations or the condition of her left shoulder. Ex. 5 at 168 – 69.

- Petitioner and the same physician scheduled another "phone visit" for January 19, 2021. Ex. 9 at 1. There are no medical records confirming that this encounter took place, however. *See generally* Exs. 4, 5.[7]

- During the next telehealth encounter on February 2, 2021, Petitioner reported **left shoulder pain.** Ex. 4 at 5. She was concerned "about when got flu and shingles shots. **Wonders if L arm soreness related… Believes L flu and R RZV."** Ex. 4 at 5 (emphasis added). The primary care physician's objective assessment was that Petitioner "provide[d] extensively detailed history." *Id.* However, he informed Petitioner that both vaccines were "documented as R deltoid." *Id.* Based on the limited information available (in the telehealth context, lacking any physical exam), he suspected that Petitioner was suffering from left shoulder impingement, for which he prescribed oxycodone-acetaminophen and provided instruction on home exercises. *Id.*; Ex. 10 at 1. At subsequent appointments, the primary care physician

[4] Shingles/ RZV is not listed on the Vaccine Injury Table. *See, e.g.*, *Fowler v. Sec'y of Health & Hum. Servs.*, No. 21-1611V, 2023 WL 5952034, at *1 (Fed. Cl. Spec. Mstr. Aug. 17, 2023) (internal citations omitted).

[5] Petitioner was 64 years old with no history of left upper extremity pain or dysfunction, or other relevant medical history according to the parties. Ex. 1 at ¶ 6; Response at 2; *see also* Ex. 5 at 145 – 167 (pre-vaccination primary care records). She is noted to be right-handed. *See, e.g.*, Ex. 4 at 69.

[6] The primary care practice had imposed a "COVID-19 restriction on number of providers working onsite simultaneously." *See, e.g.*, Ex. 5 at 168.

[7] *But see* Ex. 1 at ¶ 10 (Petitioner's recollection of this being the first date that she informed Dr. Pehling of "pain and soreness in my left arm that never healed itself after having the flu shot in my left arm").

continued to record Petitioner's complaints of a **left shoulder injury caused by a left-sided flu vaccine administration.** *See, e.g.*, Ex. 4 at 11 – 12, 24 – 25, 49 – 50.

- On March 16, 2021, an occupational therapist recorded Petitioner's history of "decreased left shoulder ROM due to shingles shot received in Dec. 2020." Ex. 4 at 14. However, the context was an initial evaluation for treating Petitioner's chronic bilateral carpal tunnel syndrome. *Id.* at 7, 14 - 17.

- At a January 14, 2022, initial evaluation, an orthopedist recorded Petitioner's history **of left shoulder pain for the past year, "associated with the flu shot that she received [in her] left shoulder prior to symptomatology.** It is the only thing that she can connect to current symptoms… No known trauma or injury." Ex. 4 at 55 (emphasis added).

- On March 2, 2022, upon starting physical therapy ("PT") for **her left shoulder,** Petitioner reported that **it had been "normal" until her "last flu shot [on…] 12/2/2020."** Ex. 4 at 69, 75 (emphasis added).

- Petitioner **declined further flu vaccinations.** *See, e.g.*, Ex. 4 at 57.[8] She also **declined steroid injections to treat her left shoulder.** *See, e.g.*, Ex. 5 at 203, 215, 221, 242; Ex. 7 at 38.

- In April 2023, Petitioner recalled that on December 5, 2020, she had specifically asked the nurse to administer only one vaccine in each arm. Ex. 1 at ¶ 7. Petitioner recalled that she received the shingles vaccine in her right arm, first and without incident. *Id.* The nurse then administered the flu vaccine in her left arm, which was followed immediately by "excruciating" pain, which she reported to the nurse. *Id.* Petitioner also recalled informing her primary care physician that the medical record indicating that both vaccines were given in her right shoulder was incorrect, while seeking treatment for her left shoulder injury. *Id.* at ¶ 10. She maintains that she would never "let anyone give me two vaccines in the same arm," after studying the subject as part of her college major in medical administration. *Id.*

- A daughter, two neighbors, and her employer also recall Petitioner's complaints, beginning in December 2020, that a left-sided administration of a flu vaccine had injured her left shoulder. These individuals did not personally observe the

[8] Petitioner did receive three vaccine doses to protect against COVID-19 on March 31, April 28, and October 27, 2021 – but their administration site is not recorded. Ex. 4 at 21, 26; Ex. 6 at 12.

vaccination, but they all observed her left shoulder injury within approximately the first month thereafter. *See generally* Exs. 12 – 16.

Respondent correctly observes that the primary care practice's computerized immunization history represents that the at-issue flu vaccine was administered in Petitioner's non-injured right arm. Respondent further contends that Petitioner "has not persuasively demonstrated that [this] record is more likely than not an error" - and that to do so, Petitioner would need a supporting statement from the vaccine administrator, as seen in the *Mezzacapo* case. Response at 8, citing *Mezzacapo v. Sec'y of Health Servs.*, No. 18-1977, 2021 WL 1940435, at *2 (Fed. Cl. Spec. Mstr. Apr. 19, 2021).

The Act, however, contains no such evidentiary requirement, nor does it otherwise set forth in black and white the precise evidence required to corroborate a situs of administration contention. Rather, resolving such issues depends on the mix of evidence before the special master. In addition (based particularly upon my experience resolving SPU cases - over 2,000 since my appointment as Chief Special Master), it is not unusual for the information regarding site of vaccination as set forth in computerized systems to be incorrect. Many of these systems use a 'dropdown' menu which may not be updated each time a separate vaccine is administered to a different individual. *See, e.g., Mezzacapo*, 2021 WL 1940435, at *6; *Desai v. Sec'y of Health & Human Servs.*, No 14-0811V, 2020 WL 4919777, at *14 (Fed. Cl. Spec. Mstr. July 30, 2020); *Rodgers v. Sec'y of Health & Human Servs.*, No. 18-0559V, 2020 WL 1870268, at *5 (Fed. Cl. Spec. Mstr. Mar. 11, 2020); *Stoliker v. Sec'y of Health & Human Servs.*, No. 17-0990V, 2018 WL 6718629, at *4 (Fed. Cl. Spec. Mstr. Nov. 9, 2018). Thus, although such records are unquestionably the first-generated documents bearing on issues pertaining to situs, they are not per se reliable simply *because* they come first – and in fact the nature of their creation provides some basis for not accepting them at face value.

This case involves such a computerized record, as well as the administration of *two vaccines* on the same day. In previous cases, the practice of vaccine administrators has been to administer one vaccine in each arm. *See, e.g.*, *Rodgers*, 2020 WL 1870268, at *5. Here, Petitioner recalls that she asked to receive one vaccine in each arm on December 2, 2020 – a credible assertion, especially because it is supported by the records from her prior vaccination encounters (which Respondent has not challenged).

Also worthy of consideration are the medical records reflecting Petitioner's consistently-reported history of a left-sided administration of the flu vaccine, which in her view, caused her left shoulder injury. While that history was first obtained two months

post-vaccination,[9] it was provided for the purposes of obtaining medical care.[10] There is no evidence to suggest that Petitioner was not acting in good faith, and her primary care physician's "objective" assessment was that she was a good historian. And while the four witnesses did not personally observe the vaccination, their statements somewhat "fill in the gap" regarding Petitioner's belief that the flu vaccine was administered on her left side, contrary to what was initially recorded.

Overall, the evidence does not dictate a finding that on December 2, 2020, both the shingle and flu vaccines were administered in Petitioner's right arm. Rather, Petitioner has presented preponderant evidence that the flu vaccine was instead most likely administered in her left, subsequently injured arm.

## Conclusion and Scheduling Order

Petitioner previously planned to file updated medical records and determine the components of any potential demand (specifically whether a lien exists). Status Report filed Dec. 22, 2023 (ECF No. 15). She should be sure to complete those tasks. And although it is not clear whether Petitioner's injury meets all criteria for a Table SIRVA, given my above finding of fact and my preliminary review of the evidence, it would be appropriate for Petitioner to promptly convey a demand and any necessary supporting documentation for Respondent's consideration. **Petitioner shall file a status report updating on her progress by no later than Friday, April 5, 2024.**

Respondent previously reported that his medical review was complete, and he requested to file his Rule 4(c) report within 60 days. Status Report filed Feb. 26, 2024 (ECF No. 18). **Accordingly, Respondent shall file the Rule 4(c) Report – or alternatively, a status report updating on his position and requesting suspension of the deadline for the Rule 4(c) Report – by no later than Monday, April 29, 2024.**

**IT IS SO ORDERED.**

**s/Brian H. Corcoran**
Brian H. Corcoran
Chief Special Master

[9] Petitioner's initial two-month delay in documenting her left shoulder injury and the intervening medical encounter for unrelated concerns does not render her history of the site of vaccination unreliable. But those circumstances do suggest that the injury could be self-managed and was less severe than some other shoulder injuries I have adjudicated – factors relevant to whatever damages might be awarded.

[10] The Federal Circuit has stated that "[m]edical records, in general, warrant consideration as trustworthy evidence . . . [as they] contain information supplied to or by health professionals to facilitate diagnosis and treatment of medical conditions." *Cucuras*, 993 F.2d at 1528 (emphasis added).